

REMARKS

Claims 21-35 are pending, and are presented for further consideration in view of the following remarks.

Rejections under § 103(a) over Moe in view of Angell

Claims 21-23, 28, and 31-35 stand rejected on the assertion that they are obvious over Moe et al. (U.S. Patent Publication 2003/0023302) and Angell et al. (U.S. Patent No. 3,983,581). Claims 24-26 are rejected as being obvious over Moe et al. and Angell et al., further in view of Rosen (U.S. Patent No. 4,345,340). Claim 27 is rejected as being obvious over Moe et al. and Angell et al. further in view of Gupta (U.S. Patent No. 4,851,000). Claims 29-30 are rejected on the assertion that they are obvious over Moe et al. in view of Angell et al. further in view of Pavcnik (U.S. Publication No. 2001/0039450).

As agreed by Examiners Schillinger and Sweet during the interview, the combination of Moe et al. and Angell et al. does not teach or suggest a “biological prosthesis comprising an aortic valve obtained from an animal, through which aortic valve blood flows in a single direction, the aortic valve having a tubular outer wall, and at least one intraparietal reinforcement device comprising a rod implanted in said tubular outer wall of said aortic valve, the rod penetrating the thickness of the tubular outer wall of said aortic valve,” as recited in independent Claim 21.

As discussed during the interview, Moe et al. discloses a polymeric valve draped over a reinforcing stent. The stents 16 (and tabs 13) of Moe et al. are not implanted in the valve body 12 but rather are placed in a space between two layers of a polymer (see Fig. 1 A depicting tabs 13 positioned in a space between two layers of the polymeric valve body 12). Thus, Moe et al. fails to disclose “an *intraparietal* reinforcement device comprising a rod penetrating the thickness of the tubular outer wall of [an] aortic valve,” the aortic valve being “obtained from an animal,” as required by independent Claim 21.

Similarly, in Angell et al., the frame struts 24, 25, 26 do not penetrate the tissue. Instead, the valve is sutured along the interior surface of the frame. (See Angell et al., Column 5, lines 30-46). Thus, neither Moe et al. nor Angell et al. discloses or fairly suggests an “*intraparietal* reinforcement device” as required by independent Claim 21.

Therefore, even taken together, Moe et al. and Angell et al. fail to disclose the combination of features recited in independent Claim 21.

Furthermore, as discussed during the interview and as attested to in the Declaration by Dr. Norman Jaffe submitted on December 29, 2008, one skilled in the art would not have considered modifying the device of Moe et al. by using the porcine valve described in Angell et al., instead of the polymeric material taught by Moe et al. because the modified device would not function for its intended use as a bioprosthetic heart valve. (See Declaration at Paragraph 8).

In addition, the Moe et al. reference itself teaches away from using natural tissue (see paragraph [0004], stating that tissue valves “tend to calcify and structurally degrade over time,” and that polymer valves “are less prone to natural variations in size and wall thickness than tissue valves.”) Thus, the inventors on the Moe application themselves did not envision using natural tissues in the devices disclosed in their patent application.

In view of the foregoing, Applicant respectfully submits that one of skill in the art would not have combined these references in the manner suggested by the Office Action.

For the foregoing reasons, Applicants submit that the present rejection of Claims 21-23, 28, and 31-35 over Moe et al. in combination with Angell et al. has been overcome. Applicant further submits that the cited references Rosen (cited as teaching a heart valve with commissure points), Gupta (cited as teaching heart valves coated with fluoropolymer), and Pavcnik (cited as teaching helical-shaped implants) include no teachings overcoming the deficiencies noted above.

Claims 22-35 depend, directly or indirectly, from independent Claim 21 and each recites a unique combination of features not taught or suggested by the cited art. Applicant submits that these claims are patentable for at least the same reasons that the claim from which they depend is patentable over the applied art. Therefore, allowance of Claims 21-35 is respectfully requested.

No Disclaimers or Disavowals

Although the present communication may include alterations to the application or claims, or characterizations of claim scope or referenced art, Applicant is not conceding in this application that previously pending claims are not patentable over the cited references. Rather, any alterations or characterizations are being made to facilitate expeditious prosecution of this application. Applicant reserves the right to pursue at a later date any previously pending or other

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broader or narrower claims that capture any subject matter supported by the present disclosure, including subject matter found to be specifically disclaimed herein or by any prior prosecution. Accordingly, reviewers of this or any parent, child or related prosecution history shall not reasonably infer that Applicant has made any disclaimers or disavowals of any subject matter supported by the present application.

CONCLUSION

For the foregoing reasons, it is respectfully submitted that the rejections set forth in the outstanding Office Action are inapplicable to the present claims. Accordingly, early issuance of a Notice of Allowance is most earnestly solicited.

The undersigned has made a good faith effort to respond to all of the noted rejections and to place the claims in condition for immediate allowance. Nevertheless, if any undeveloped issues remain or if an issue requires clarification, the Examiner is respectfully requested to call Applicant's attorney in order to resolve any such issue promptly.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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